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| 10/775,277 | 02/10/2004 | Marshall Sherman | 11350.41 | 1231 |

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| EXAMINER | |
|---|---|
| TOY, ALEX B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3739 | |

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/775,277 | SHERMAN, MARSHALL | |
| | Examiner | Art Unit | |
| | Alex B. Toy | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 8-9, 11, 14-17, and 19-23* is/are rejected.

7)☒ Claim(s) *4, 6-7, 10, 12-13, 18 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/04, 6/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS: 12/30/04, 3/14/05*.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 15, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by LePivert (U.S. Pat. No. 6,235,018 B1).

Regarding claim 1, LePivert discloses a method for assessing an ice ball formation during the cryoablation of a target tissue in the vasculature of a patient, said method comprising the steps of:

providing a cryocatheter 112 having a cryotip 106 (Fig. 5);

contacting said patient with a reference electrode 30 (Fig. 4);

positioning said cryotip proximate said target tissue;

measuring a first impedance between said cryotip and said reference electrode (col. 6, ln. 21-33);

cooling said cryotip;

measuring a second impedance between said cryotip and said reference electrode after said cooling step (col. 6, ln. 21-23); and

determining a ratio of said first impedance to said second impedance to assess the formation of an ice ball and an extent of the cryoablation of target tissue (col. 5, ln. 45 – col. 6, ln. 12).

Regarding claim 5, LePivert discloses the method of claim 1 wherein said cryotip includes an expansion chamber and said step of cooling said cryotip is accomplished by expanding a refrigerant in said expansion chamber (col. 8, ln. 45-48 and Fig. 6). The expansion chamber is formed by the space between the inner tube 166 and the outer shaft 160 (Fig. 6).

Claim 15 invokes the means-plus-function language of 35 U.S.C. 112, 6th paragraph in claiming means for positioning and means for cooling. Therefore, claim 15 is interpreted to include any structures "equivalent" to structures described in the specification for performing the functions claimed. See *In re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994).

Regarding claim 15, LePivert discloses a system for assessing ice ball formation during the cryoablation of a target tissue of a patient, said system comprising:

a reference electrode 30 for contacting said patient (Fig. 4);

a cryocatheter 112 having a cryotip 106 (Fig. 5);

a cryocatheter 112 as a means for positioning said cryotip proximate said target tissue(Fig. 5);

an inner tube 166 delivering cryogenic fluid as a means for cooling said cryotip to create an ice ball and cryoablate said target tissue (col. 8, ln. 45-51 and Fig. 6);

an electronic means 26 connected to said cryotip 28 and said reference electrode 30 to measure an impedance therebetween to assess formation of said ice ball (col. 6, ln. 21-28 and Fig. 4).

Claim 19 invokes the means-plus-function language of 35 U.S.C. 112, 6th paragraph in claiming means for expanding and means for cooling. Therefore, claim 19 is interpreted to include any structures "equivalent" to structures described in the specification for performing the functions claimed. See *In re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994).

Regarding claim 19, LePivert discloses the system of claim 15 wherein said cryotip is formed with an expansion chamber and said means for cooling said cryotip includes a means for expanding a refrigerant in said expansion chamber (col. 8, ln. 45-48 and Fig. 6). The expansion chamber is formed by the space between the inner tube 166 and the outer shaft 160 and provides a means for the refrigerant to expand (Fig. 6). The inner tube 166 delivers cryogenic fluid as a means for cooling said cryotip.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-3, 9, 11, 16-17, are rejected under 35 U.S.C. 103(a) as being unpatentable over LePivert.

Regarding claim 2, LePivert discloses the method of claim 1 wherein said first and second impedance are measured using one or more frequencies (col. 5, ln. 11-15). The claim differs from LePivert in calling for the a signal to specifically have a frequency of approximately 20 kHz. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to have used a signal having a frequency of approximately 20 kHz, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, applicant has not disclosed any unique criticality to this value or that it uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that could not be achieved with other values. Finally, it is noted that McRae (U.S. Pat. No. 5,069,223) uses a signal range of 10kHz – 30 MHz to measure impedance over time to monitor the progress of cryogenic treatment of practically any tissue in the body (col. 3, ln. 5-13 and 38-40).

Regarding claim 3, LePivert discloses the method of claims 1 and 2 wherein said signal has an unspecified voltage (col. 6, ln. 21-26). The claim differs from LePivert in calling for the a signal to specifically have an RMS voltage of approximately 0.5 V. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to have used a signal having an RMS voltage of approximately 0.5

V, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, applicant has not disclosed any unique criticality to this value or that it uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that could not be achieved with other values. Finally, it is noted that McRae uses an RMS voltage range of 10 mV to 1.54 V to measure impedance over time to monitor the progress of cryogenic treatment of practically any tissue in the body (col. 9, ln. 61 and col. 3, ln. 38-40).

Regarding claim 9, LePivert discloses a method for assessing an ice ball formation during the cryoablation of a target tissue of a patient, said method comprising the steps of:

contacting the patient with a reference electrode 30 (Fig. 4);

providing a cryocatheter 112 having a cryotip 106 (Fig. 5);

cooling said cryotip to create an ice ball and cryoablate said target tissue (col. 8, ln. 45-51 and Fig. 6);

generating a measurement signal having a frequency and a voltage (col. 6, ln. 21-26); and

using said measurement signal to measure a current between said cryotip and said reference electrode to assess the formation of said ice ball (col. 6, ln. 21-28).

The claim differs from LePivert in calling for the signal to have a frequency in the range of 15 to 25 kHz and an RMS voltage of less than 1.0 V. It would have been

obvious, however, to one having ordinary skill in the art at the time the invention was made to have used a signal with a frequency in the range of 15 to 25 kHz and an RMS voltage of less than 1.0 V, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, applicant has not disclosed any unique criticality to these values or that it uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that could not be achieved with other values. Finally, it is noted that McRae uses a signal with a frequency range of 10kHz – 30 MHz and an RMS voltage range of 10 mV to 1.54 V to measure impedance over time to monitor the progress of cryogenic treatment of practically any tissue in the body (col. 3, ln. 5-13 and 38-40).

Regarding claim 11, the method of claim 9 is obvious in view of LePivert as stated in the preceding rejection of claim 9. In addition, LePivert discloses the method of claim 11, wherein said cryotip includes an expansion chamber and said step of cooling said cryotip is accomplished by expanding a refrigerant in said expansion chamber (col. 8, ln. 45-48 and Fig. 6). The expansion chamber is formed by the space between the inner tube 166 and the outer shaft 160 (Fig. 6).

Regarding claim 16, LePivert discloses the system of claim 15 wherein said electronic means measures said impedance using a signal having one or more frequencies (col. 5, ln. 11-15). The claim differs from LePivert in calling for the a signal to specifically have a frequency of approximately 20 kHz. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to

have used a signal having a frequency of approximately 20 kHz, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, applicant has not disclosed any unique criticality to this value or that it uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that could not be achieved with other values. Finally, it is noted that McRae uses a signal range of 10kHz – 30 MHz to measure impedance over time to monitor the progress of cryogenic treatment of practically any tissue in the body (col. 3, ln. 5-13 and 38-40).

Regarding claim 17, LePivert discloses the system of claims 15 and 16 wherein said signal has an unspecified voltage (col. 6, ln. 21-26). The claim differs from LePivert in calling for the a signal to specifically have an RMS voltage of approximately 0.5 V. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to have used a signal having an RMS voltage of approximately 0.5 V, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, applicant has not disclosed any unique criticality to this value or that it uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that could not be achieved with other values. Finally, it is noted that McRae uses an RMS voltage range of 10 mV to 1.54 V to measure impedance over

time to monitor the progress of cryogenic treatment of practically any tissue in the body (col. 9, ln. 61 and col. 3, ln. 38-40).

Claims 8, 14, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over LePivert in view of Sun et al. (U.S. Pat. No. 6,391,024).

Regarding claim 8, LePivert discloses the method of claim 1 comprising a reference electrode 30 (Fig. 4). The claim differs from LePivert in calling for the reference electrode to specifically be a backplate. Sun et al., however, teach an analogous method of monitoring ablation using two electrodes to measure impedance, wherein the reference electrode is a backplate 16 (col. 16, ln. 40-42 and Fig. 8a). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the reference electrode of LePivert to be a backplate in view of the teachings of Sun et al. because using a backplate as a reference electrode is well known in the art (col. 1, ln. 60-67).

Regarding claim 14, the method of claims 9 is obvious in view of LePivert as stated in the preceding rejection of claim 9. In addition, LePivert discloses a reference electrode 30 (Fig. 4). The claim differs from LePivert in calling for the reference electrode to specifically be a backplate. Sun et al., however, teach an analogous method of monitoring ablation using two electrodes to measure impedance, wherein the reference electrode is a backplate 16 (col. 16, ln. 40-42 and Fig. 8a). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the reference electrode of LePivert to be a backplate in view of the

teachings of Sun et al. because using a backplate as a reference electrode is well known in the art (col. 1, ln. 60-67).

Regarding claim 20, LePivert discloses the system of claim 15 comprising a reference electrode 30 (Fig. 4). The claim differs from LePivert in calling for the reference electrode to specifically be a backplate. Sun et al., however, teach an analogous system for monitoring ablation using two electrodes to measure impedance, wherein the reference electrode is a backplate 16 (col. 16, ln. 40-42 and Fig. 8a). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the reference electrode of LePivert to be a backplate in view of the teachings of Sun et al. because using a backplate as a reference electrode is well known in the art (col. 1, ln. 60-67).

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. in view of LePivert.

Regarding claim 21, Sun et al. disclose a method for assessing contact between a tip of an ablation catheter and a target tissue in the vasculature of a patient, said method comprising the steps of:

contacting said patient with a reference electrode 16 (col. 16, ln. 40-42 and Fig. 8a);

positioning said tip proximate said target tissue;

measuring a first impedance between said tip and said reference electrode;

moving said tip relative to said target tissue;

measuring a second impedance between said tip and said reference electrode; and

determining a ratio of said first impedance to said second impedance to assess contact between said tip and said target tissue.

See col. 3, ln. 34-62 for a description of the above steps.

The claim differs from Sun et al. in calling for the ablation catheter to specifically be a cryocatheter. LePivert, however, teach an analogous method for assessing the extent of the cryoablation of a target tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the ablation catheter of Sun et al. to be a cryocatheter in view of LePivert because cryoablation is an obvious alternate method of ablation that is well known in the art.

Regarding claim 22, Sun et al. disclose the method of claim 21 in view of LePivert. The claim differs from Sun et al. in calling for the a signal to specifically have a frequency of approximately 20 kHz. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to have used a signal having a frequency of approximately 20 kHz, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, applicant has not disclosed any unique criticality to this value or that it uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that could not be achieved with other values. Finally, it is noted that McRae uses a signal range of 10kHz – 30 MHz to measure impedance over time to

monitor the progress of cryogenic treatment of practically any tissue in the body (col. 3, ln. 5-13 and 38-40).

Regarding claim 23, Sun et al. disclose the method of claims 21 and 22 in view of LePivert. The claim differs from Sun et al. in calling for the signal to specifically have an RMS voltage of approximately 0.5 V. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to have used a signal having an RMS voltage of approximately 0.5 V, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, applicant has not disclosed any unique criticality to this value or that it uniquely provides an advantage, is used for a particular purpose, or solves a stated problem that could not be achieved with other values. Finally, it is noted that McRae uses an RMS voltage range of 10 mV to 1.54 V to measure impedance over time to monitor the progress of cryogenic treatment of practically any tissue in the body (col. 9, ln. 61 and col. 3, ln. 38-40).

### ***Allowable Subject Matter***

Claims 4, 6-7, 10, 12-13, 18, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pat. No. 6,190,378 B1 to Jarvinen
U.S. Pat. No. 6,471,693 B1 to Carroll et al.
U.S. Pat. No. 6,551,309 B1 to LePivert
U.S. PGPub 2005/0038422 A1 to Maurice

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
8/17/05

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